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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/786,937	01/22/1997	PHILIPPE BOUCHARD	235299/96001	5859
909	7590	08/27/2002		
PILLSBURY WINTHROP, LLP P.O. BOX 10500 MCLEAN, VA 22102			EXAMINER DELACROIX MUIRHEI, CYBILLE	
			ART UNIT 1614	PAPER NUMBER 33
			DATE MAILED: 08/27/2002	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	08/786,937	BOUCHARD ET AL.
	Examiner	Art Unit
	Cybille Delacroix-Muirheid	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 04 September 2001 and 05 June 2002.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 15, 16, 18-24 and 26-37 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 15, 16, 18-24 and 26-37 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____ .

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### **DETAILED ACTION**

1. Claims 15, 16, 18-24, 26-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diedrich et al. in view of Felberbaum et al.
2. Claims 21, 22 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Diedrich et al.
3. Claims 15, 16, 18-24, 26-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-25, 30, 31, 33, 36-39, 41-48 of copending Application No. 09/053,152.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Amendment***

The following is responsive to Applicant's amendment and remarks received Sep. 4, 2001 and June 5, 2002.

No claims are cancelled. No new claims are added.

Claims 15, 16, 18-24, 26-37 are currently pending.

The previous claims objections set forth in paragraphs 2-3 of the office action mailed Oct. 24, 2000 are withdrawn in view of Applicant's amendment received Sep. 4, 2001.

The previous provisional double patenting rejection set forth in paragraphs 9-10 of the office action mailed Oct. 24, 2000 is maintained until receipt of a Terminal Disclaimer.

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The previous double patenting under 35 USC 101 set forth in paragraphs 11-12 of the office action mailed Oct. 24, 2000 is withdrawn in view of Applicant's response received June 5, 2002.

However, Applicant's arguments traversing the previous claims rejections under 35 USC 102(b) and 35 USC 103(a) set forth in paragraphs 4-8 of the office action mailed Oct. 24, 2000 have been considered but are not found to be persuasive.

Said rejections are maintained essentially for the reasons given previously in the office action mailed Oct. 24, 2000 with the following additional comment:

It is essentially Applicant's position that Diedrich and Felberbaum do not teach an improved method for treating infertility disorders by administering a single or dual dose of 1 to 10 mg or multiple doses of 0.1 to 0.5 mg. Applicant also argues that the dosages for suppressing LH surges in Diedrich are higher than is claimed by Applicant. Applicant additionally argues that a preferred multiple dose posology representing a dose of 0.1-0.5, preferably 0.25 mg Cetrorelix on cycle day 6 may be used in the claimed invention.

Concerning the Felberbaum reference, Applicant argues that Felberbaum administers higher amounts of Cetrorelix (cycle day 7 at 3 mg or 1 mg daily up to ovulation) than the claimed invention. Felberbaum also fails to recognize the importance FSH secretion at natural levels and therefore does not disclose a dose of LHRH antagonist capable of suppressing LH without affecting FSH secretion. Furthermore, the sustained dosages taught by Diedrich and Felberbaum would not have achieved the claimed methods of treating fertility disorders.

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Said arguments have been considered but are not found to be persuasive.

Concerning Applicant's arguments that the dosages of Cetrorelix taught by Diedrich and Felberbaum are higher than the claimed invention, i.e. 0.1-0.5 mg, preferably 0.25 mg on cycle day 6, said arguments are not commensurate in scope with the claimed methods, especially claim 18. Furthermore, Applicant's claims are in the alternative. For example, claims 15 and 21 require a single or dual dose of LHRH antagonist/Cetrorelix in an amount between 1 and 10 mg or in a multiple dosage of 0.1 to 0.5 mg. Both Diedrich and Felberbaum disclose Applicant's claimed dosage amounts by teaching the administration of Cetrorelix at 3 mg or 1 mg daily (starting on day 7, see claims 49, 50) and furthermore, Felberbaum suggests the use of lower dosages by teaching that premature LH surges can be avoided with doses as low as .5 mg/day. Therefore, the Examiner respectfully maintains that it would have been obvious to one of ordinary skill in the art to use the method taught by Diedrich to treat infertility because Felberbaum raises expectation of success by disclosing that ovarian stimulation is induced and further because Felberbaum, in addition to Diedrich, teaches that the disclosed treatment results in suppression of LH surges and "satisfactory follicular maturation" and thus would allow for ovulation induction in patients at high risk of Ovarian Hyperstimulation Syndrome and Polycystic Ovary Disease. Additionally, both Diedrich and Felberbaum disclose administration of the same gonadotropin/Cetrorelix combination at Applicant's claimed dosages to a patient using the same method steps set forth in Applicant's claims. Accordingly, treatment of fertility disorders would have been obvious.

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***Claim Rejections - 35 USC § 112***

4. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 19 recites the limitation "inhibition of action of natural LH is caused by Cetrorelix" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

***Claim Objections***

6. Claim 18 is objected to because of the following informalities: in claim 18, line 3, after "improvement", the term "being" should be deleted and replaced with --comprising--. Appropriate correction is required.

***Conclusion***

Claims 15, 16, 18-24, 26-37 stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703)

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306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM



Aug. 26, 2002



Cybille Delacroix-Muirheid  
Patent Examiner Group 1600